

UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF NEW YORK

-----X
DOUGLAS SCHOTTENSTEIN, et al.,

Plaintiffs,

22-cv-10883 (PKC)

-against-

ORDER

EDWARD L. CAPLA, et al.,

Defendants.

-----X
CASTEL, U.S.D.J.

Plaintiff is a medical doctor licensed in New York and Florida who specializes in neurology and pain management. He alleges that defendant Orthogen International GmbH (“Orthogen”) and other defendants conspired to defraud him and to avoid regulation by the Food and Drug Administration of Regenokine®, which plaintiff alleges is a drug, pharmaceutical or other modality subject to its administrative oversight and regulation through the FDA’s Center for Biologics Evaluation and Research.

Plaintiff asserts that he had been a licensee of the “Regenokine® Program” since 2012 but that his license was wrongfully terminated on March 24, 2020, more than two-and-a-half years ago. He also refers to attempted poisoning with antifreeze occurring in January 2020. (Complaint ¶ 54.) While not outright alleging defendants’ direct involvement in the administration of poison, he insinuates it by placing the allegation immediately below the heading “Acts in Furtherance of the Conspiracy; the Poisoning of Dr. Schottenstein.”

Plaintiff has submitted a proposed Order to Show Cause for a preliminary injunction motion, together with a proposed temporary restraining Order. The Complaint fails to plausibly allege subject matter jurisdiction.

Plaintiff asserts the following four claims for relief: Count I, “Tortious Interference,” apparently with plaintiff’s Regenokine® license; Count II, “Fraud and Deceit with Civil Conspiracy;” Count III, “Injunctive Relief”, apparently against certain defendants who may commence litigation in Germany;¹ and Count IV, “Unjust Enrichment, an Accounting and Imposition of Constructive Trusts.”² Diversity of citizenship is not alleged as a basis for subject matter jurisdiction. Indeed, the citizenship of plaintiff and the eight individual defendants are not alleged. Orthogen is alleged to be organized under the laws of Germany with its principal place of business in Dusseldorf.

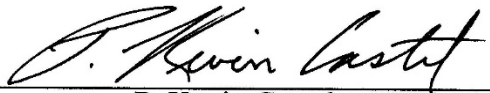
The FDA and its Acting Commissioner are named as “nominal defendants” but no claim is asserted against them. In the body of the complaint, plaintiff alleges that “to fail to undertake investigation and testing of Regenokine®, and to impose its process under which approval to use Regenokine®, for treatment of patients may be rejected, approved or approved with conditions and exclusions, and to stay the use of Regenokine®, on patients pending the outcome of the administrative and regulatory process, constitutes non-compliance with the aforesaid statutory and regulatory requirements” imposed on the FDA. (Complaint ¶ 186.) In a conclusory manner, he alleges federal question jurisdiction, but none of the four claims for relief arise under the Constitution or federal law. Plaintiff does not allege any substantive claim against the FDA or its Commissioner, nor has he demonstrated how he would have standing to do so or how this Court would have jurisdiction in the absence of any exhausted administrative remedy.

¹ Neither New York nor any cited federal law provides for a standalone claim for injunctive relief. Rather, injunctive relief may be a remedy for a substantive claim

² While the concept of a nominal defendant is known in certain discrete areas of law, e.g. shareholders derivative action, the purported claims asserted here are not among them.

The Court declines to issue the proposed Order to Show Cause because a review of the Complaint demonstrates, at least preliminarily, that the Court lacks subject matter jurisdiction. If plaintiff wishes to continue to pursue injunctive relief, he shall (1) submit a memorandum of law by January 6, 2023 demonstrating that the Court has subject matter jurisdiction; (2) demonstrate why the Court ought to set a hearing on a preliminary injunction motion relating to a license terminated on March 24, 2020 and a medical procedure that has been in use since at least 2012; and (3) serve a copy of this Order and the proposed order to show cause and all papers on which it is based, including the complaint, on all defendants by electronic means and overnight courier by 3 p.m. on December 29, 2022.³

SO ORDERED.


P. Kevin Castel
United States District Judge

Dated: New York, New York
December 28, 2022

³ Any defendant previously served with the proposed order to show cause and all papers on which it is premised, including the complaint, need only be served with this Court's Order. See Donner Declaration.